DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 29, 2014

MedShape, Incorporated
Mr. Jack Griffis
Vice President, Research & Development
1575 Northside Drive NW, Suite 440
Atlanta, Georgia, 30318

Re: K141290
Trade/Device Name: *Helical Ridge* Bone Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI
Dated: August 27, 2014
Received: August 29, 2014

Dear Mr. Griffis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number:** K141290

**Device Name:** *Helical Ridge* Bone Anchor

**Indications for Use:**

The MedShape PEEK Interference Screw is intended for soft tissue to bone reattachment in surgeries of the shoulder, elbow, foot/ankle, knee, and hand/wrist. Specifically;

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon Reconstruction, Tendon Transfers in the Foot and Ankle

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal Joint Arthroplasty (Basal Thumb Joint Arthroplasty), Carpal Ligament Reconstructions and Repairs, Tendon Transfer in the Hand/Wrist

| Prescription Use ___X____ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
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Concurrence of CDRH, Office of Device Evaluation (ODE)

K141290

# 510(k) Summary

Date Submitted: September 22nd, 2014

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(e).

A. Submitter:
MedShape, Inc.
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318

B. Company Contact:
Jack Griffis
VP, Research & Development
(678) 235-3311 (direct)
(404) 249-9158 (fax)
jack.griffis@medshape.com

C. Device Information:
Trade Name(s): *Helical Ridge* Bone Anchor
MedShape PEEK Interference Screw

Common Name(s): Fastener, Fixation, Bone

D. Classification Name: Fastener, Fixation, Non-degradable, Soft Tissue
HWC/MBI 21 CFR 888.3040

E. Predicate Device(s):
MedShape, Inc., *Morphix*® Suture Anchor, K091202
MedShape, Inc., *Eclipse* Soft Tissue Fastener, K123350
Arthrex SwiveLock® Bone Anchor, K101823
Arthrex Tenodesis Product Family, K051726

F. Physical Description:
The proposed *Helical Ridge* Bone Anchor is a sterile, single use, orthopedic implant intended to be used for fixation of soft tissue to bone.

The *Helical Ridge* Bone Anchor is comprised of PEEK. The anchor is provided sterile and pre-loaded on a disposable driver handle.

G. Indications for Use:

The MedShape PEEK Interference Screw is intended for soft tissue to bone reattachment in surgeries of the shoulder, elbow, foot/ankle, knee, and hand/wrist. Specifically;

K141290

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon Reconstruction, Tendon Transfers in the Foot and Ankle

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal Joint Arthroplasty (Basal Thumb Joint Arthroplasty), Carpal Ligament Reconstructions and Repairs, Tendon Transfer in the Hand/Wrist

H. Comparison of Technological Characteristics:

The *Helical Ridge* Bone Anchor is substantially equivalent in function and intended use to the following predicate devices:

MedShape, Inc., *Morphix*® Suture Anchor, K091202
MedShape, Inc., *Eclipse* Soft Tissue Fastener, K123350
Arthrex *SwiveLock*® Bone Anchor, K101823
Arthrex Tenodesis Product Family, K051726

All anchors are comprised of implant grade PEEK. All anchors have the same indications for use. In addition, functional performance testing to confirm substantial equivalence as follows:

- Monotonic soft tissue fixation strength in Sawbone® bone analogue
- Dimensional verification testing for product samples
- Material safety testing (both biocompatibility and MRI compatibility).

Analysis of the results supports the conclusion that the proposed device is substantially equivalent to the predicate devices.

Jack Griffis
VP, Research & Development

MEDSHAPE
1575 Northside Drive, Suite 440
Atlanta, GA 30318
877-343-7016 phone
404-249-9158 fax